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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,402	03/01/2006	Rajeev Shankar Mathur	RLL-274US	1976

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RANBAXY INC.
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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
12/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,402	MATHUR ET AL.	
	Examiner	Art Unit	
	Ali Soroush	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7,9,11,13,20,22-28,36,37,40 and 44-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7,9,11,13,20,22-28,36,37,40 and 44-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's preliminary amendment filed on 01/18/2005 is acknowledged.

Status of the Claims

Claims 4-6, 8, 10, 12, 14-19, 21, 29-35 38, 39, and 41-43 have been cancelled. Therefore, claims 1-3, 7, 9, 11, 13, 20, 22-28, 36, 37, 40, and 44-54 are currently pending examination for patentability.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 7, 9, 11, 13, 46, 47, 48, 52, 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Dandiker et al. (US Patent 542590, Publication 06/20/1995).

Dandiker et al. teach "a controlled release pharmaceutical composition comprising: (a) an outer layer comprising a pH dependent hydrophilic polymer together with one or more fillers; and (b) one or more inner layers each comprising an active ingredient ... and processes for the preparation thereof." (See abstract). "The pharmaceutical compositions according to the invention may be prepared according to conventional methods known in the art using conventional tabletting machinery." (See column 10, Lines 60-63). "Sumatriptan was dry mixed with microcrystalline cellulose and lactose and the mixture was granulated using a granulating fluid composed of

polyvinylprrolidone dissolved in isopropyl alcohol. The granulate was dried in a fluid bed drier, sieved and blended with sodium stearyl fumerate before compression on a suitable tablet press to produce 100 mg core tablets containing 50 mg of sumatriptan (as succinate) which were 5.5 mm in diameter and 3.0 mm in thickness." (See column 15, Lines 14-22). "The excipients for the polymer layer were dry mixed and the core tablet was compression coated using the resulting blend to produce 340 mg tablets, 9.0 mm in diameter and 4.1 mm in thickness." (See column 15, Lines 33-36). Dandiker et al. teach that an example of a suitable filler/ diluent is microcrystalline cellulose, a suitable binder is polyvinylpyrrolidone, and a suitable lubricant is sodium stearyl fumerate. (See column 5, Lines 43-45, 51-54 and column 6, Lines 20-24). "When pharamceutical compositions of the invention (i.e. tablets) are provided with an enteric coating this will delay the initiation of the erosion/disintegration of the underlying pH independent hydrophilic polymer layer until the table reaches a region of the gastrointestinal tract where a specific pH prevails." (See column 6, Lines 36-41). "Enteric coatings for use in the tablets of the invention will be those coatings known to those skilled in the art. Such coatings include ... shellac ...." (See column 6, Lines 45-48). Dandiker et al. further teach, "the serotonin S_2-agonsit sumatriptan ... is a compound having a combination of highly advantageous properties for the treatment of migraine." (See column 1, Lines 41-46). With regard to the tablet being taste-masked, this property is inherent to the tablet. The instant claims is not distinguishable from the prior art and therefore it would be expected that tablet with the same components would

also have the property of being taste-masked. For the foregoing reasons the instant invention is anticipated by the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 23, 49, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al. (US Patent 542590, Publication 06/20/1995).

Applicant Claims

Applicant claims a process for the preparation of a sumatriptan tablet comprising granulating sumatriptan with diluents and/or binders; mixing granules with pharmaceutically acceptable excipients and compressing the mixture into a tablet. Wherein, the tablet can further comprise a second active ingredient. The applicant further claims the tablet and a method of treating migraines using the prepared tablet.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Dandiker et al. are disclosed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Dandiker et al. does not anticipate a tablet comprising sumatriptan and a second active agent. However, Dandiker et al. does make the addition of a second active agent to the tablet obvious.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to add a second active agent to the tablet taught by Dandiker et al. One would have been motivated do so because Dandiker et al. teach that the tablets of there invention can have more than one inner layer and each layer can comprise an active agent. Therefore, it would have been obvious to one of ordinary skill to add a second active agent that would help in the treatment of migraines in order to administer multiple drugs simultaneously for the treatment of migraines. For the foregoing reasons the instant invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

2. Claims 2, 20, 22, 37, 40, 44, 45, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al. (US Patent 542590, Publication 06/20/1995) in view of Jordan (US Patent 5389129, Published 02/14/1995).

Applicant Claims

Applicant claims a process for the preparation of a sumatriptan tablet comprising granulating sumatriptan with diluents and/or binders; mixing granules with pharmaceutically acceptable excipients and compressing the mixture into a tablet. Wherein, the tablet can further comprise a second active ingredient and a wax polish. The applicant further claims the tablet and a method of treating migraines using the prepared tablet.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Dandiker et al. are disclosed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Dandiker et al. does not teach the tablet having a wax polish. This deficiency is cured by the teachings of Jordan.

Jordan teaches, "a wax polish composition, such a wax polish composition for pharmaceutical tablet ..." (Se column 1, Lines 1-3). "The present invention provides in a first aspect a polish composition comprising beeswax, carnauba wax, water and an emulsifier." (See column 1, Lines 36-38). "The polish compositions of the present invention may be used to coat tablets with a layer of wax to impart a gloss to the tablet surface, and any of the conventional tablet coating methods may be used ..." (See

column 5, Lines 21-24). The polish is also applied "to impart a pharmaceutically acceptable finish." (See column 1, Lines 34-35).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Dandiker et al. with Jordan. One would have been motivated to do so because Jordan et al. teaches that any pharmaceutical tablet can be wax polished in order to give an acceptable finish or gloss to the tablet. With regard to the claim (claims 22, 40, and 45) limitation that the tablet comprises up to about 10% w/w based on the total weight, polish wax. Jordan is silent as to amount of wax polish to be added to the tablet. It would have been obvious to one of ordinary skill in the art to adjust the amount of wax polish being applied to the tablet in order to achive the desired gloss and/or finish, through routine experimentation. For the foregoing reasons the instant invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

3. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al. (US Patent 542590, Publication 06/20/1995) in view of Stamm et al. (International Application Published Under the PCT WO 98/31360, Published 07/23/1998).

Applicant Claims

Applicant claims a process for the preparation of a sumatriptan tablet comprising spraying a solution or suspension of sumatriptan and diluents and/or binders in a solvent onto inert cores to form a first layer, blending the core with pharmaceutically acceptable excipients, and compressing the blend to form a tablet. Wherein, the tablet can further comprise a second layer of diluents and/or binders.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Dandiker et al. are disclosed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Dandiker et al. does not teach the tablet being formed by spraying a solution of sumatriptan, binder and/or diluent onto inert cores. This deficiency is cured by the teachings of Stamm et al.

Stamm et al. teaches "a composition comprising (a) an inert hydrosoluble carrier covered with at least one layer containing an active ingredient ... and (b) optionally one or several outer phase(s) or layers(s) ... also a method for preparing said composition." (See abstract). "The method according to the invention is prepared by a novel process comprising spraying a suspension of the ingredient in micronized form in a solution of hydrophilic polymer and, optionally, a surfactant onto the inert cores." (See page 10, Lines 23-26). "Th[e] suspension is prepared by putting the micronized active ingredient into suspension in a solution comprising the hydrophilic polymer and, optionally, a

surfactant, in solution in solvent." (See page 12, Lines 2"5). "The solvent employe can be aqueous or organic (for example ethanol). For example demineralized water can be used." (See page 12, Lines 16-18). "The composition according to the invention can additionally contain any excipient conventionally used in the pharmaceutical ... fields which is compatible with the active ingredient, such as binders, filler, pigments, disintegrating agents, lubricants, wetting agents, buffers, etc." (See page 8, Lines 32-37). "When the granulate obtained (whether subsequently coated or not) is compressed to form tablets, this step can be implemented using any conventional technique which is suitable." (See page 11, Lines 33-36). "Th[e] outer layer comprises conventional excipients." (See page 9, Line 16). "The term 'active ingredient' is used in this document in its conventional sense and thus covers every substance having pharmacological, therapeutic, etc. activity." (See page 7, Lines 7-9). The method of producing the tablet composition has the advantage of improving the dissolution profile and bioavailability of the active ingredient and thereby reducing the does required to be administered. (See page 1, Lines 29-31).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Dandiker et al. with Stamm et al. One would have been motivated to do so because Dandiker et al. teaches that any conventional means can be used to prepare the sumatriptan tablet. Further, the method of producing the tablet composition taught by Stamm et al. increases the dissolution

profile and bioavailability of the active ingredient. Therefore, one of ordinary skill in the art would combine the teachings of Dandiker et al. with Stamm et al. if one wanted to produce a tablet of sumatriptan with a increased dissolution profile and bioavailability. For the foregoing reasons the instant invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

4. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al. (US Patent 542590, Publication 06/20/1995) in view of Stamm et al. (International Application Published Under the PCT WO 98/31360, Published 07/23/1998) further in view of Jordan (US Patent 5389129, Published 02/14/1995).

Applicant Claims

Applicant claims a process for the preparation of a sumatriptan tablet comprising spraying a solution or suspension of sumatriptan and diluents and/or binders in a solvent onto inert cores to form a first layer, blending the core with pharmaceutically acceptable excipients, and compressing the blend to form a tablet. Wherein, the tablet can further comprise a second layer of diluents and/or binders and wax polish.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The combined teachings of Dandiker et al. and Stamm et al. are disclosed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

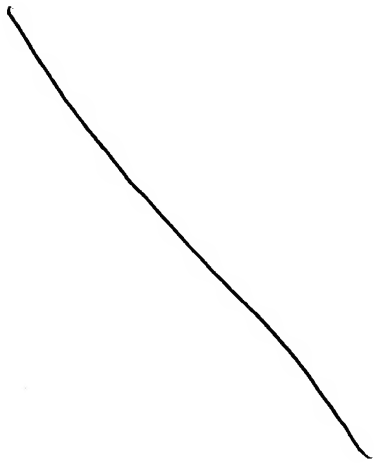
The combined teachings of Dandiker et al. and Stamm et al. do not teach the tablet having a wax polish. This deficiency is cured by the teachings of Jordan.

Jordan teaches, "a wax polish composition, such a wax polish composition for pharmaceutical tablet ..." (Se column 1, Lines 1-3). "The present invention provides in a first aspect a polish composition comprising beeswax, carnauba wax, water and an emulsifier." (See column 1, Lines 36-38). "The polish compositions of the present invention may be used to coat tablets with a layer of wax to impart a gloss to the tablet surface, and any of the conventional tablet coating methods may be used ..." (See column 5, Lines 21-24). The polish is also applied "to impart a pharmaceutically acceptable finish." (See column 1, Lines 34-35).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Dandiker et al. and Stamm et al. with Jordan. One would have been motivated to do so because Jordan et al. teaches that any pharmaceutical tablet can be wax polished in order to give an acceptable finish or gloss to the tablet. With regard to the claim (claims 22, 40, and 45) limitation that the tablet comprises up to about 10% w/w based on the total weight, polish wax. Jordan is silent as to amount of wax polish to be added to the tablet. It would have been obvious to one of ordinary skill in the art to adjust the amount of wax polish being applied to the tablet in order to achive the desired gloss and/or finish, through routine experimentation.

For the foregoing reasons the instant invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.



Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

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